

# EXHIBIT Q



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Health Resources and Services  
Administration

Rockville, MD 20857

MAR 1 2018

Mr. Motty Shulman  
Bois Schiller Flexner LLP  
333 Main Street  
Armonk, NY 10504

Dear Mr. Shulman:

Thank you for your letter regarding Tamiany de La Rosa and the Organ Procurement and Transplantation Network (OPTN) liver allocation policy. The Health Resources and Services Administration (HRSA) oversees the OPTN, which develops organ allocation policies through a deliberative process with input from experts in the field, transplant candidates and recipients, donor and recipient families, living donors, and the public. HRSA considers your letter a critical comment under 42 CFR § 121.4(d), and is providing this response after consideration of the OPTN's deliberations and actions taken by the OPTN Board of Directors to change the liver allocation policy at its meeting on December 4, 2017.

On December 4, 2017, the OPTN Board of Directors (OPTN Board) considered and voted to approve a proposal by the OPTN Liver and Intestine Transplantation Committee (Liver Committee) modifying the OPTN Liver Allocation Policy. The meeting was open to the public and additional information may be found at: <https://optn.transplant.hrsa.gov/news/board-approves-enhanced-liver-distribution-system/>.

The OPTN Final Rule (42 CFR part 121) requires the OPTN to develop policies for the equitable allocation of organs among potential recipients. Per the OPTN Final Rule, OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and not be based on a candidate's place of residence or listing except to the extent required to satisfy other factors. HRSA has not advocated for any specific policy solution, since we rely on the expertise of the OPTN and transplant community to assess these factors as organ allocation policies are created and changed.

OPTN has reviewed and updated its organ allocation policies over the last 15 years, including the liver allocation policy, to support the equitable allocation of organs among transplant candidates while considering the evolving advances in transplantation. The development of the current liver allocation and distribution policy began in 2012 when the OPTN Board determined that geographic disparities in liver allocation were unacceptably high. Following were several years of policy discussion, modeling of numerous potential approaches, a series of public meetings, and public comment on a draft policy proposal in 2016. Subsequently, HRSA encouraged the OPTN leadership and leaders in the transplant community to consider options to address the OPTN Final Rule requirements while taking into account the concerns of stakeholders, including patients, liver transplant programs, and organ procurement organizations.

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After the 2016 policy proposal, OPTN sought further feedback from the transplant community to address stakeholder concerns. HRSA encouraged the OPTN leadership to consider all viewpoints while moving the policy development process forward in accordance with the requirements of the OPTN final rule.

The OPTN Liver Committee reviewed models prepared by the Scientific Registry for Transplant Recipients, and after voting, posted a new draft proposal on the OPTN website. This draft proposal was available for public comment from July 31, 2017, through October 2, 2017. The proposal is accessible at <https://optn.transplant.hrsa.gov/governance/public-comment/enhancing-liver-distribution>.

The Liver Committee then met on October 10, 2017, and voted against that version of the proposal and instead voted to advance a modified proposal to the OPTN Board for a final vote. The modified proposal was subsequently approved by the OPTN Board in December 2017. Modeling predicts that the new liver allocation policy will decrease the variation across the country of the requisite severity of a candidate's disease in order to be offered a liver for transplantation, as compared to current practice.

HRSA appreciates your interest in the transplantation program, which facilitated more than 33,500 total transplants in 2016, a 20 percent increase over the past 5 years. HRSA will continue to monitor developments regarding proposed changes to OPTN's liver allocation policy to ensure compliance with the National Organ Transplant Act of 1984, as amended, and the OPTN Final Rule.

Sincerely,

A handwritten signature in blue ink that reads "George Sigounas". The signature is fluid and cursive, with the first name "George" and last name "Sigounas" clearly distinguishable.

George Sigounas, MS, Ph.D.  
Administrator